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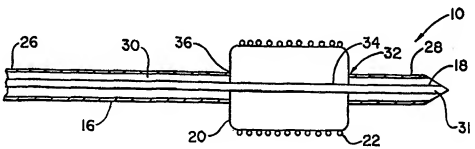

(57) Abstract

A balloon catheter withs stent placement recess generally comprises a catheter shaft with a recess defined by an elongate base and sides that are substantially perpendicular to the base. The sides of the recess extend between the elongate base and the outer diameter of the catheter shaft. An inflatable balloon is secured to the catheter shaft and is maintained within the recess when not inflated. A stent, wrapped about the balloon, is also maintained within the recess when the balloon is not inflated. The recess within the catheter shaft and its ability to maintain the balloon and stent prevents slipping of the stent relative the balloon and thus, improper placement of the stent within the vasculature. The recess also maintains the slim profile of the catheter shaft and prevents unwanted stretching and tearing of the vasculature by the catheter prior to stent placement.

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BALLOON CATHETER WITH STENT PLACEMENT RECESS

Cross-References to Related Applications

This application claims priority under 35 U.S.C. § 119(e) to, and hereby incorporates by reference, U.S. Provisional Application No. 60/074,063, filed 9 February 1998.

Field of the Invention

This invention relates to catheters and more particularly, dilatation balloon catheters for stent implantation.

Background of the Invention

Various types of catheters are used to perform varied medical procedures. One of the most widely used catheters is that of a dilatation balloon catheter for angioplasty procedures. In recent years, angioplasty has gained widespread acceptance and use as a technique for treating atherosclerotic coronary and peripheral vascular diseases. According to the angioplasty technique, a first dilatation balloon catheter is percutaneously introduced into the patient's vasculature under fluoroscopic control. The first balloon catheter generally incorporates an undersized balloon that is used to pre-dilate or create a channel in which to pass the stent through without damaging the vasculature. The balloon is usually selected at a diameter that is approximately 0.5 mm less in diameter than that of the artery it will be dilating. With the passageways of the vasculature widened, the first catheter is removed. Next, a second dilatation balloon catheter, incorporating a low pressure balloon and surrounding stent, is percutaneously introduced through the pre-dilated passageway to reach the desired location and lightly embed the stent within the vasculature. With the stent in position, the low pressure balloon is removed, and a high pressure balloon is inserted. Once in position, the high pressure balloon is inflated by pneumatic pressure to dilate the stenosis, expand and implant the stent, and thereby relieve the obstruction to blood flow. The high pressure balloon is then deflated and

removed.

Conventional dilatation balloon catheters for stent placement use balloons and accompanying stents that are maintained to the exterior diameter of the catheter body and that are crimped to or attached to the catheter in some fashion that enables undesirable sliding of the stent during positioning. The sliding of the stent can result in improper placement of the stent and potential damage to a patient's vascular structure. Catastrophe can occur if the stent slides completely off the balloon catheter during insertion. Further, a balloon and stent that is maintained to the exterior diameter of the catheter body adds additional and unwanted bulk to the profile of the catheter which may cause undesirable stretching and/or tearing of the vasculature.

There is, therefore, a need for a balloon catheter with a stent recess or retention means that can perform the function of two catheters, e.g. widening passageways and dilating a stenosis, as well as provide protection to the stent to prevent the sliding and/or complete loss of the stent during placement, and maintain a slim profile during insertion of the catheter.

Summary of the Invention

The problems indicated above are in large measure solved by the balloon catheter with the stent placement recess of the present invention. The balloon catheter with stent placement recess generally comprises a catheter shaft that is defined by a proximal and distal end, and an inner and outer diameter. Intermediate the proximal and distal ends is a recess. The recess is defined by an elongate base and sides that are approximately perpendicular to the elongate base. The length of the sides extends between the elongate base and the outer diameter of the catheter shaft. An inner shaft is placed inside the catheter shaft and creates an inflation lumen between the inner shaft and the catheter shaft. A balloon is secured to the catheter shaft so as to receive inflation fluid from the inflation lumen. The balloon is maintained within the recess when it is not inflated. A stent is wrapped about the balloon and is also maintained

within the recess when the balloon is not inflated.

Description of the Drawings

Fig. 1 depicts a side sectional view of a balloon catheter with stent placement recess of the present invention with the balloon inflated.

Fig. 2 depicts a side sectional view of the balloon catheter with stent placement recess of the present invention with the balloon deflated.

Detailed Description of the Invention

Referring to Figures 1 and 2, a balloon catheter 10 with stent placement recess or retention means may be appreciated. Balloon catheter 10 with stent placement recess generally comprises a catheter shaft 16, an inner shaft 18, a balloon 20 and stent 22.

Catheter shaft 16 has a proximal end portion 26 and a distal end portion 28. The catheter shaft 16 diameter is preferably less than or equal to about three French, e.g., 3F. Catheter shaft 16 surrounds an inner shaft 18. The space between catheter shaft 16 and inner shaft 18 comprises an inflation lumen 30 while the space interior to inner shaft 18 comprises a guidewire lumen 31. Balloon 20 is secured to catheter shaft 16 so as to receive inflation fluid from inflation lumen 30. Stent 22 is wrapped about balloon 20. Balloon 20 is preferably a high pressure balloon, capable of inflation to sixteen or more atmospheres.

Intermediate proximal and distal end portions 26, 28 of catheter shaft 16 is defined an area for said retention means, which, in one embodiment, is a recess 32. Recess 32 incorporates an elongate base portion 34, which is preferably in the range of 6-40 mm in length, and perpendicular side portions 36. Balloon 20 and stent 22 are maintained within said recess and generally do not extend beyond the maximum diameter of the catheter shaft 16 while the catheter 10 is being positioned within the vasculature, or during the times of non-inflation. The ability of recess 32 to retain balloon 20 and stent 22 during the non-inflation period prevents stent 22 from sliding relative to balloon 20 and also prevents improper placement of stent 22 within the vasculature. Further,

the positioning of balloon 20 and stent 22 within the area of a retention means having a smaller catheter profile than adjacent catheter wall portions, such as recess 32, prevents unwanted stretching and tearing of the vasculature that may otherwise occur using a balloon and stent that extend the exterior diameter of the catheter during the non-inflation period.

The preferred procedural use of balloon catheter 10 is as follows: (1) a first balloon catheter, utilizing an undersized balloon, is used to pre-dilate or create a channel within the vasculature to allow for passage of stent balloon catheter 10 without damage to the vasculature; and (2) balloon catheter 10 with stent 22 is introduced to the pre-dilated passageway and inserted until stent 22 is in the desired location at which time balloon 20 is expanded by pneumatic pressure to dilate the stenosis, and to expand and implant stent 22. Balloon 20 is then deflated and removed. Noticeably, the preferred procedural use of balloon catheter 10 with recessed stent 22 has eliminated one significant step of the standard, prior art procedure. Namely, the intermediate step of using a low pressure balloon to pre-position stent 22 prior to use of the high pressure balloon to embed stent 22. The procedure could additionally be reduced to a single step if catheter 10 and recessed stent 22 were of a low enough profile to eliminate the need for a pre-dilation catheter.

In the above embodiment, balloon 20 is retained within a recess 32. However, alternative embodiments of the invention encompass the concept of stent 22 being retained relative to the catheter shaft 16 by any type of effective indentation, e.g. built-up portions around the circumference of the catheter shaft 16, located at each end of stent 22 to retain stent 22. The use of built-up portions may undesirably expand the overall diameter of the catheter and as such, the appropriate embodiment should be chosen in view of the application at hand.

Note that balloon catheter with recess for stent 10 may be used as a pre-dilation catheter with or without the stent 22 present.

The present invention may be embodied in other specific forms

without departing from the spirit of the essential attributes thereof; therefore, the illustrated embodiment should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

WHAT IS CLAIMED:

1. A balloon catheter for stent placement, comprising:
a catheter shaft varying in profile;
an inner shaft within said catheter shaft defining an inflation lumen
between said inner shaft and said catheter shaft;
a balloon, having an inflation and non-inflation state, secured to said
catheter shaft so as to receive an inflation fluid from said inflation lumen for inflation; and
a stent placed about said balloon and retained within a retention area
defined by said balloon and said catheter shaft while said balloon is in its non-inflation state, said retention area having a smaller profile than the largest profile of said catheter.

2. A balloon catheter for stent placement, comprising:
a catheter shaft having a proximal and a distal end, an inner and outer diameter, and a retention area defined intermediate to said proximal end and said distal end, said retention area having an elongate base and sides that are substantially perpendicular to said elongate base, the length of said sides defined by the distance between said elongate base and said outer diameter of said catheter shaft;
an inner shaft defining an inflation lumen between said inner shaft
and said catheter shaft;
a balloon, having an inflation state and a non-inflation state, the balloon being secured to said catheter shaft so as to receive an inflation fluid from said inflation lumen for inflation, said balloon retained within said retention area during said

non-inflation state; and

a stent placed about said balloon and maintained within said retention area during said balloon's non-inflation state.

3. A catheter for implanting a stent in a patient's vasculature, the catheter comprising a catheter shaft and an inner shaft, the catheter and inner shafts cooperating to define an inflation lumen, the catheter shaft defining a first portion with a first diameter and a second portion with a second diameter, the first diameter being smaller than the second diameter, the catheter shaft including means for retaining a stent, the stent retaining means comprising a balloon and at least partially defined by the first and second portions such that a diameter of the stent is substantially less than or equal to the second diameter when the balloon is not inflated, the catheter being configured to convey the vascular stent to a site in the patient's vasculature and to implant the stent at the site utilizing a low profile approach.

4. The catheter of claim 3, in which the inner shaft defines a guidewire lumen.

5. The catheter of claim 3, in which the inflation balloon is in fluid communication with the inflation lumen.

6. The catheter of claim 3, in which the second diameter is about 3 French.

7. The catheter of claim 3, in which the second diameter is less than about 3 French.

8. The catheter of claim 3, the retaining means further including a generally elongate base portion extending along the first catheter

portion.

9. The catheter of claim 3, the retaining means further including at least one side portion extending between the first and second portions.

10. A method for implanting a stent in a patient's vasculature, the method comprising the steps of:

providing a stent disposed about a balloon on a catheter, the catheter comprising:

first and second catheter shafts cooperating to define an inflation lumen, the first catheter shaft defining a first portion and a second portion, a diameter of the first portion being smaller than a diameter of the second portion, the first catheter shaft including means for retaining the stent defined by the first and second portions and comprising a balloon, the catheter being configured to convey the stent to a site in the patient's vasculature;

maneuvering the stent disposed about the balloon on the catheter to a site within the patient's vasculature; and

inflating the balloon, thereby implanting the stent in the inner luminal wall of the vasculature.

11. The method of claim 10, further comprising the step of pre-dilating the vasculature.

12. The method of claim 10, further comprising the step of introducing the catheter and stent into the patient's vasculature.

13. The method of claim 10, further comprising the step of deflating the balloon.

14. The method of claim 13, further comprising the step of removing the balloon catheter from the patient's vasculature after implanting the stent.

Fig. 1

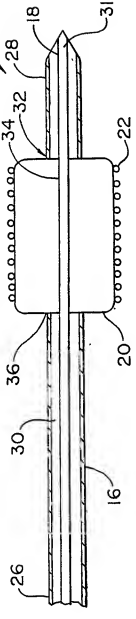

Fig. 2